K061702

510(k) Summary for the
Dimension Vista™ System Creatine Kinase Calibrator
(CK CAL – KC340)

JUL 10 2006

A. 510(k) Number:

B. Analyte: Creatine Kinase (CK).

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Creatine Kinase Calibrator
(CK CAL – KC340)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Clinical Chemistry

G. Intended Use: The CK CAL is an *in vitro* diagnostic product for the calibration of Creatine Kinase (CK) method on the Dimension Vista™ System.

H. Device Description:

CK CAL is frozen, liquid, bovine serum albumin based product containing creatine kinase from porcine heart. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B. The volume per vial is 1.0 mL.

I. Substantial Equivalence Information:

1. Predicate Device: Dimension® Creatine KinaseVerifier (DC26) and VITROS™ Chemistry Products Calibrator Kit 3.

2. Predicate K Number(s): K861700 for Dimension® clinical chemistry system. For the Ortho-Diagnostics VITROS Calibrator Kit 3, a 510(k) was not available.

3. Comparison with Predicate:

Comparison			
Item	**Dimension Vista™ System Creatine Kinase Calibrator**	**Dimension® Creatine Kinase Verifier**	**Otho-Clinical Diagnostics VITROS™ Calibrator Kit 3**
Intended Use	The CK CAL is an *in vitro* diagnostic product for the calibration of the creatine kinase (CK) method on the Dimension Vista™ System.	The Dimension® Creatine Kinase Verifier is an in vitro diagnostic product to be used to verify the Dimension® clinical chemistry systems for the Creatine Kinase (CK) method.	For *in vitro* diagnostic use only. VITROS Calibrator Kit 3 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of AcP, ALKP, ALT, AST, **CK**, GGT, LDH and LIPA.
Analytes	Creatine Kinase	Creatine Kinase	Acid Phosphatase (AcP), alanine aminotransferase (ALT), alkaline aminotransferase (ALKP), amylase (AMYL), aspartate aminotransferase (AST), **creatine kinase (CK)**, gamma glutamyltransferase (GGT), lactate dehydrogenase (LDH) and lipase (LIPA).
Form	Liquid	Lyophilized	Lyophilized
Traceability	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.	Values assigned to VITROS Chemistry Product Calibrator Kit 3 are traceable to high quality materials.
Matrix	Bovine serum albumin based product containing creatine kinase from porcine heart.	Human serum base product containing creatine kinase from simian heart.	Bovine serum and porcine heart based product.
Levels	Two levels.	Three levels.	Three levels.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for the Dimension Vista™ Creatine Kinase Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at -20°C with control stored at -70°C. The method is calibrated from this stored material. The -20°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined where the allowable shelf life percent change should be ≤ 5 %. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board is stable for seven days.
An open vial not on instrument, but recapped and stored in a refrigerator is stable for 30 days.

   For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 1, 8, 15, 22, and 32 versus freshly opened vials.

2. Traceability: The assigned values of the Creatine Kinase Calibrator are traceable to Master Pool, Dimension® clinical chemistry system.

3. Value Assignment:

   The new calibrator Master Pool is made by gravimetrically adding quantities of creatine kinase to bovine serum albumin base to target concentrations. The concentrations are verified against a previously approved Master Pool lot. The final bottle value for the Master Pool is assigned for each level by testing N = 45 replicates on multiple instruments.
   A stock solution is prepared for the new commercial calibrator lot by gravimetrically adding quantities of creatine kinase to bovine serum albumin base to target concentrations. The stock solution is verified by comparing the recovery of the stock solution versus the Master Pool assigned bottle values.
   For the commercial calibrator lot, calculated quantities of the stock solution are added to the bovine serum albumin base to target concentrations. The concentration of each level is verified to be

within acceptable range by using an instrument calibrated with Master Pools. The final bottle value is assigned to each level and verified using a released commercial lot of calibrator on multiple instruments for N = 45 total replicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 10 2006

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc.
500 GBC Drive
PO Box 6101, M/S 514
Newark, DE 19714-6101

Re: k061702
Trade/Device Name: Dimension Vista™ Creatine Kinase Calibrator (CK Calibrator, KC340)
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: June 15, 2006
Received: June 16, 2006

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known):

Device Name:

Dimension Vista™ Creatine Kinase Calibrator (CK Calibrator , KC340)

Indications for Use:

The CK CAL is an *in vitro* diagnostic product for the calibration of Creatine Kinase (CK) method on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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